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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,173	11/20/2003	Shuji Kitamura	04703/100J586-US1	4450
7278	7590	06/16/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,173	KITAMURA ET AL.	
	Examiner Michael V. Meller	Art Unit 1655	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 17-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 7-9 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The microorganism strain, *Lactobacillus helveticus* CM4 FERM BP-6060, is required to practice the claimed invention.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited

material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.

If the deposit(s) has/have not been made under the Budapest Treaty, then to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registr. number, showing:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807;
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

It is noted by applicants that the deposit has been made under the terms of the Budapest Treaty but there is nothing on the record to reflect that an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her

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signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent was made on the record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 583 074 (abstract, page 2, line 55-page 3, line 33, the examples and the claims), JP 2782153 (abstract) or Nakamura et al. (abstract, col. 3, lines 30-40, example 1, ex. 2, ex. 3, the claims).

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The above references each teach that *Lactobacillus helveticus* is mixed with skim milk to produce fermented milk. The viscosity of the milk is inherent to the milk. They also teach that yeast can be added to the mixture as well. Note that to mix, only requires combining into one mass.

The pH limitation that applicant has added is inherent to the lactic acid bacteria that is used. For example, as can be seen in Yamamoto '796, col. 4, lines 55-end, and Yamamoto '111, col. 4, line 6-col. 5, line 5, the pH of the mixture is from 5.0 to 4.5 or lower, thus the required pH range by the claim is met since the pH range goes from 5 to 4.6. Further the claim only requires that "at least during the period when the pH of the mixture is lowered from 5 to 4.6" which encompasses higher and lower limits on both ends of the range. Since lactic acid bacteria is being used in all the references, then it would be inherent since one is using the same bacterium and using milk. See also Nakamura '661, example 1 where the same situation occurs. This claimed pH is merely a very specific pH range which all of the references will inherently go through as shown in the noted places in the noted references. The other references where it is silent would be inherent since they are processed exactly the same way with a lactic acid bacterium as the noted references and use milk to start as the claims require.

Claims 1-4, 6, 8, 9, 17-21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. '796 (title, abstract, see col. 1, col. 5, lines 5-40, col. 6, lines 15-60, col. 7, lines 1-30, ex. 2) or Yamamoto et al. '111 (col. 1, lines 1-60, col. 5, lines 15-40, col. 7, lines 5-15, col. 7, example 1, ex. 2).

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The above references each teach that *Lactobacillus helveticus* is mixed with skim milk to produce fermented milk. The fermented milk inherently contains the peptide since the same starting materials are used and since the process is the same. The viscosity of the milk is inherent to the milk. Note that to mix, only requires combining into one mass.

The pH limitation that applicant has added is inherent to the lactic acid bacteria that is used. For example, as can be seen in Yamamoto '796, col. 4, lines 55-end, and Yamamoto '111, col. 4, line 6-col. 5, line 5, the pH of the mixture is from 5.0 to 4.5 or lower, thus the required pH range by the claim is met since the pH range goes from 5 to 4.6. Further the claim only requires that "at least during the period when the pH of the mixture is lowered from 5 to 4.6" which encompasses higher and lower limits on both ends of the range. Since lactic acid bacteria is being used in all the references, then it would be inherent since one is using the same bacterium and using milk. See also Nakamura '661, example 1 where the same situation occurs. This claimed pH is merely a very specific pH range which all of the references will inherently go through as shown in the noted places in the noted references. The other references where it is silent would be inherent since they are processed exactly the same way with a lactic acid bacterium as the noted references and use milk to start as the claims require.

The limitation to centrifugation of the whey is seen on col. 7, lines 1-15 of Yamamoto '111 and Yamamoto '796.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 583 074 (abstract, page 2, line 55-page 3, line 33, the examples and the claims), JP 2782153 (abstract) or Nakamura et al. (abstract, col. 3, lines 30-40, example 1, ex. 2, ex. 3, the claims) in view of Yamamoto et al. '796 (title, abstract, see col. 1, col. 5, lines 5-40, col. 6, lines 15-60, col. 7, lines 1-30, ex. 2) or Yamamoto et al. '111 (col. 1, lines 1-60, col. 5, lines 15-40, example 1, ex. 2).

The teachings of the references are above. They do not specifically teach that the specific strain *Lactobacillus helveticus* CM4 FERM BP-6060 is used, but it would have been obvious to use such a strain since such strains are well known in the art as is evidenced by the references. It is simply the choice of the artisan to use one strain over the others. The specific strain in the references would be expected to produce the same enzyme inhibitor as that produced by *Lactobacillus helveticus* CM4 FERM BP-6060.

Thus, it is simply the choice of the artisan in an effort to optimize the results to use the specific strain, *Lactobacillus helveticus* CM4 FERM BP-6060 in stead of the strain disclosed in the references.

EP, JP and Nakamura do not teach that they can recover whey from the fermented milk.

Yamamoto '796 and Yamamoto '111 both teach that it is well known to use centrifugation to recover the whey from the fermented milk. The limitation to centrifugation of the whey is seen on col. 7, lines 1-15 of Yamamoto '111 and Yamamoto '796.

Thus, it would have been obvious to recover the whey from the milk.

Note that to mix, only requires combining into one mass.

The ph limitation that applicant has added is inherent to the lactic acid bacteria that is used. For example, as can be seen in Yamamoto '796, col. 4, lines 55-end, and Yamamoto '111, col. 4, line6-col. 5, line 5, the pH of the mixture is from 5.0 to 4.5 or lower , thus the required ph range by the claim is met since the ph range goes from 5 to 4.6. Further the claim only requires that "at least during the period when the ph of the mixture is lowered from 5 to 4.6" which encompasses higher and lower limits on both ends of the range. Since lactic acid bacteria is being used in all the references, then it would be inherent since one is using the same bacterium and using milk. See also Nakamura '661, example 1 where the same situation occurs. This claimed ph is merely a very specific ph range which all of the references will inherently go through as shown in the noted places in the noted references. The other references where it is silent

would be inherent since they are processed exactly the same way with a lactic acid bacterium as the noted references and use milk to start as the claims require.

Claims 1-9, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. '796 (title, abstract, see col. 1, col. 5, lines 5-40, col. 6, lines 15-60, col. 7, lines 1-30, ex. 2) or Yamamoto et al. '111 (col. 1, lines 1-60, col. 5, lines 15-40, example 1, ex. 2) in view of EP 583 074 (abstract, page 2, line 55-page 3, line 33, the examples and the claims), JP 2782153 (abstract) or Nakamura et al. (abstract, col. 3, lines 30-40, example 1, ex. 2, ex. 3, the claims).

The teachings of the references are above. They do not specifically teach that the specific strain *Lactobacillus helveticus* CM4 FERM BP-6060 is used, but it would have been obvious to use such a strain since such strains are well known in the art as is evidenced by the references. It is simply the choice of the artisan to use one strain over the others. The specific strain in the references would be expected to produce the same enzyme inhibitor as that produced by *Lactobacillus helveticus* CM4 FERM BP-6060. Thus, it is simply the choice of the artisan in an effort to optimize the results to use the specific strain, *Lactobacillus helveticus* CM4 FERM BP-6060 instead of the strain disclosed in the references.

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The Yamamoto references do not teach that they can use yeasts along with the bacteria to produce fermented milk. The limitation to centrifugation of the whey is seen on col. 7, lines 1-15 of Yamamoto '111 and Yamamoto '796.

EP, JP and Nakamura all teach that it is well known to use yeasts along with the claimed bacteria to produce fermented milk.

Thus, it would have been obvious to produce fermented milk using not only the bacteria and the milk but also using a yeast as taught by EP, JP and Nakamura.

Note that to mix, only requires combining into one mass.

The ph limitation that applicant has added is inherent to the lactic acid bacteria that is used. For example, as can be seen in Yamamoto '796, col. 4, lines 55-end, and Yamamoto '111, col. 4, line6-col. 5, line 5, the pH of the mixture is from 5.0 to 4.5 or lower , thus the required ph range by the claim is met since the ph range goes from 5 to 4.6. Further the claim only requires that "at least during the period when the ph of the mixture is lowered from 5 to 4.6" which encompasses higher and lower limits on both ends of the range. Since lactic acid bacteria is being used in all the references, then it would be inherent since one is using the same bacterium and using milk. See also Nakamura '661, example 1 where the same situation occurs. This claimed ph is merely a very specific ph range which all of the references will inherently go through as shown in the noted places in the noted references. The other references where it is silent would be inherent since they are processed exactly the same way with a lactic acid bacterium as the noted references and use milk to start as the claims require.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael V. Meller
Primary Examiner
Art Unit 1655

MVM